



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|-----------------------|---------------------|------------------|
| 09/697,306 | 10/27/2000 | James F. McGuckin JR. | 10546/53003 | 4213 |

30636 7590 11/07/2003
FAY KAPLUN & MARCIN, LLP
150 BROADWAY, SUITE 702
NEW YORK, NY 10038

| |
|----------|
| EXAMINER |
|----------|

DAWSON, GLENN K

| | |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

3761

DATE MAILED: 11/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/697,306

Applicant(s)

MCGUCKIN, JAMES F.

Examiner

Glenn K Dawson

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 49-51 is/are allowed.
- 6) ☒ Claim(s) 36-48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Art Unit: 3761

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 36-38, 40-44 and 46-48 are rejected under 35 U.S.C. 102(e) as being anticipated by Kuramoto, et al.-5395030.

Kuramoto discloses an endoscopic stapler having a capsule 5,6, with a stapling mechanism and a cutter. A scope 61 is placed inside the capsule and extends through the shaft 67 to the operating handle. A grasping forceps 150 acts to pull tissue into the location between the stapler and anvil. The capsule is inserted into the large intestine through the anus-see col. 8 lines 16-18.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

Art Unit: 3761

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 36-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsuruta-'098 in view of Sauer-'694 and Kessel-'673.

Tsuruta discloses a flexible endoscopic stapler see col. 34 lines 6-15. An operating capsule has a stapling mechanism and a cutter. However, the grasping forceps and the internal endoscope is not disclosed. Sauer discloses the use of internal forceps to pull tissue into the cutting field. It would have been obvious to have provided Tsuruta with an internal forceps to pull tissue into the stapling and cutting field.

Kessel discloses a forceps with an internal endoscope. It would have been obvious to have provided the device of Tsuruta as modified by Sauer with an internal endoscope, as taught by Kessel, as this would have afforded the device the ability to display the immediate operative field to the physician.

As the scope is slidable relative to the forceps and stapler, to have used the scope as a guide would have been an obvious method step as the scope would be used to identify the proper surgical area and the device could be threaded thereover. In the event that the tissue to be stapled and cut were not at the proper location relative to the staples and cutter, to have repositioned the tissue by using the forceps would have been an obvious method step to ensure that the proper tissue were excised.

Response to Arguments

Applicant's arguments filed 09-02-03 have been fully considered but they are not persuasive.

The newly amended claim language in the apparatus claims merely adds functional limitations. No further structural limitations were provided. If the prior art is deemed to be capable of performing the claimed functions, then the prior art anticipates the claims. The examiner maintains that the flexible forceps of Kuramoto could easily be directed to grasp a full thickness fold of tissue and pull it into a cutting zone or the space between the stapler and the anvil, even though this is not shown, because as shown in fig. 25, the forceps could be directed to a position misaligned with the anvil projection 147 and could grasp a fold of tissue with its jaws.

As stated by the examiner before, Tsuruta clearly discloses that the stapler can be flexible or rigid. Tsuruta goes on to state in col. 34 lines 8-12 that if flexible, the components extending through it from the operating section (control handle) for operating the stapler may be flexible to bend. Both flexible endoscopes, and flexible endoscopic instruments had been known for years before applicant's filing date and the

Art Unit: 3761

manner in which to manufacture Tsuruta's device in a flexible embodiment would have been readily apparent to one of skill in the art.

Although not necessary for the present rejection, the examiner considers it obvious to have made Sauer's device flexible. However, one skilled in the art would recognize that the teachings of an inner forceps for grasping and placing tissue into a working zone of an instrument would be equally applicable to rigid and flexible devices.

The examiner is unable to understand applicant's arguments with respect to Kessel. Clearly endoscope 11 is flexible as shown in fig.1 and given the disclosure that the endoscope can be repeatedly inserted into the endoscope channel, requiring the endoscope to be flexible.

The coupling structure for coupling the endoscope to the head would merely be the lumen receiving the scope.

The arguments as to the allowability of the method claims is persuasive as the prior art does not disclose or make obvious the grasping of a full thickness fold of tissue and drawing it into a tissue-receiving chamber within the head, stapling the abutting portions of the tissue and resecting the selected portion of tissue from the abutting portions of the grasped folded tissue.

Terminal Disclaimer

The terminal disclaimer filed on 07-02-02 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of 5,868,760 or 6,264,086 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Allowable Subject Matter

Claims 49-51 are allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Glenn K Dawson whose telephone number is 703-308-4304. The examiner can normally be reached on M-Th 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weilun Lo can be reached on 703-308-1957. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Art Unit: 3761

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.



Glenn K Dawson
Primary Examiner
Art Unit 3761

Gkd
05 November 2003